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10 UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
11
12 SAN FRANCISCO DIVISION

13 UNITED STATES OF AMERICA,
14 Plaintiff,
15 v.
16 GOLDEN GATE SOY PRODUCTS, INC., a
17 corporation; YONG LI CHEN, an individual;
and LING HONG TANG, an individual,
18 Defendants.
19

**COMPLAINT FOR PERMANENT
INJUNCTION**

20 The United States of America, Plaintiff, by and through its undersigned attorneys, respectfully
21 represents as follows:

22 **INTRODUCTION**

23 1. The United States of America brings this action on behalf of the United States Food and
24 Drug Administration (“FDA”) pursuant to the Federal Food, Drug, and Cosmetic Act (the “Act”), 21
25 U.S.C. § 332(a), to permanently enjoin and restrain Golden Gate Soy Products, Inc. (“Golden Gate
26 Soy”), Yong Li Chen, and Ling Hong Tang (collectively, “Defendants”), from violating 21 U.S.C. §
27 331(k), by causing food to become adulterated within the meaning of 21 U.S.C. § 342(a)(4), while such
28 Complaint for Permanent Injunction

1 food is held for sale after shipment of one or more of its components in interstate commerce.

2 **JURISDICTION AND VENUE**

3 2. This Court has jurisdiction under 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and
4 1345, and personal jurisdiction over all parties.

5 3. Venue in this district is proper pursuant to 28 U.S.C. § 1391(b) and (c).

6 **INTRADISTRICT ASSIGNMENT**

7 4. The conduct at issue in this action took place in substantial part in San Francisco
8 County.

9 **DEFENDANTS**

10 5. Defendant Golden Gate Soy Products, Inc., is a California corporation with its
11 headquarters at 1265 Griffith Street, San Francisco, California 94124-3408. The company
12 manufactures and distributes a variety of tofu and other soy-based products, such as marinated bean
13 cake, soy milk, and tofu pudding. The company was incorporated on or about May 16, 2016. Its
14 current owners are Defendant Yong Li Chen, Defendant Ling Hong Tang, and three other individuals
15 who reside in China.

16 6. Defendant Yong Li Chen is a co-owner, as well as the Chief Executive Officer and
17 President, of Golden Gate Soy. She resides part-time in China and part-time in California. When in
18 China, she oversees Golden Gate Soy's acquisition of equipment, packaging, labels, and suppliers.
19 When in California, she handles sales and works on the production floor at Golden Gate Soy.
20 Defendant Chen also has authority to hire and fire employees and make purchases, and is involved in
21 making decisions regarding corrective actions in production.

22 7. Defendant Ling Hong Tang is a co-owner and the Chief Financial Officer of Golden
23 Gate Soy. She is present at the firm every day. Her responsibilities include monitoring production and
24 sanitation, coordinating production operations, overseeing production scheduling, planning, and
25 purchasing, and handling accounting and administrative duties. Defendant Tang also has authority to
26 hire and fire employees and make purchases, and she approves all large purchases. She also oversees
27 the pest control services, worked with the manufacturers of the company's new automated equipment to

1 ensure it was working properly before it was used, and purchases all raw and packaging materials.

2 **LISTERIA MONOCYTOGENES**

3 8. *Listeria monocytogenes* (“*L. mono*”) is common in soil and moist environments. If
4 cleaning and sanitizing in a food manufacturing facility is inadequate, *L. mono* can colonize the facility.
5 When colonization occurs, normal processing activities may result in food becoming contaminated with
6 *L. mono* from the environment. Unlike many other food-borne microbes, *L. mono* bacteria can adapt
7 and grow at refrigerated temperatures. Consequently, *L. mono* is a significant public health risk in
8 ready-to-eat foods, such as Defendants’ tofu and other soy-based products, and difficult to eliminate
9 once present.

10 9. *L. mono* can cause adverse health effects in consumers, such as listerial gastroenteritis,
11 or a more serious condition known as invasive listeriosis. While *L. mono* infects a comparatively small
12 number of people each year, the life-threatening effects of an *L. mono* infection make it one of the
13 leading causes of death from foodborne illness, with an approximately 20 percent fatality rate.

14 10. Populations with impaired or weaker immune systems, including pregnant women,
15 infants, the elderly, persons with AIDS, and persons taking certain immunosuppressive medications,
16 face the greatest risk when eating food contaminated with *L. mono*. In pregnant women, an *L. mono*
17 infection can cause miscarriage, fetal death, or severe illness or death in a newborn infant. In older
18 susceptible children and adults, infection often has an impact on the central nervous system and blood
19 stream. *L. mono* infection may also lead to meningitis, septicemia, endocarditis, and pneumonia.

20 **DEFENDANTS’ VIOLATIONS**

21 11. Defendants violate 21 U.S.C. § 331(k) by causing food held for sale after shipment of
22 one or more components in interstate commerce to become adulterated within the meaning of 21 U.S.C.
23 § 342(a)(4).

24 12. Defendants’ tofu and other soy-based products are food within the meaning of 21 U.S.C.
25 § 321(f).

26 13. Defendants receive soybeans—the main raw ingredient in their tofu and soy-based
27 products—from a supplier located in Missouri.

14. Food manufactured by Defendants is adulterated within the meaning of 21 U.S.C. § 342(a)(4), in that it has been prepared, packed, and held under insanitary conditions whereby it may have become contaminated with filth. The insanitary conditions include the prolonged presence of *L. mono* at Defendants' facility, persistent pest infestation, and dirty food processing equipment.

FDA INSPECTIONS

15. FDA's San Francisco District Office has inspected Defendants' facility three (3) times since 2017, most recently in February 2019. FDA laboratory analyses of samples collected during these inspections revealed the presence of *L. mono* in the facility. These inspections have also established that Defendants have an extensive history of operating under insanitary conditions and continue to violate the Act.

February 2019 Inspection

16. FDA conducted its most recent inspection of the facility on February 6-8, 12, and 19, 2019, as a follow-up inspection to previous inspections (described below) finding insanitary conditions. During the inspection, FDA investigators observed numerous insanitary conditions including, but not limited to, the following:

(a) Defendants do not have a written food safety plan with each element required by law. *See* 21 C.F.R. § 117.126.

(b) Defendants do not conduct their operations under conditions and controls necessary to minimize the potential for food contamination. *See* 21 C.F.R. § 117.80(c). FDA investigators observed, among other things, condensate dripping from pipes in the production area and in a doorway through which uncovered food is moved, food and equipment coming into contact with dirty surfaces, and employees using equipment that had not been cleaned or sanitized.

(c) Defendants do not clean or sanitize utensils or equipment as frequently as necessary to protect against food contamination. *See* 21 C.F.R. § 117.35(d). FDA investigators observed, among other things, the use of equipment that had food residue on it.

(d) Defendants do not clean or sanitize utensils or equipment in a manner that protects against contamination. *See* 21 C.F.R. § 117.35(a). FDA investigators observed, among other

1 things, an employee clean a floor with a high-pressure hose in such a manner as to cause soymilk from
2 the floor to splash onto clean production tables.

3 (e) Defendants do not maintain their facility in a clean and sanitary condition or keep
4 the facility in good repair. *See* 21 C.F.R. § 117.35(a). FDA inspectors observed, among other things,
5 peeling paint on the production walls, liquid pooling on the production floor, cracks and chips in the
6 production floor, and black residue on the production walls.

7 (f) Defendants do not take reasonable measures or precautions related to personnel
8 practices. *See* 21 C.F.R. § 117.10. FDA investigators observed, among other things, an employee's
9 wristwatch and arm coming in direct contact with finished food product during packaging, an employee
10 performing maintenance on the tofu press table while it was in use during production, and an employee
11 placing a metal tool on top of a stack of metal pans filled with soybean curds during production.

12 (g) Defendants do not have adequate sanitary facilities and accommodations. *See* 21
13 C.F.R. § 117.37. FDA investigators observed, among other things, an employee-handwashing sink
14 without paper towels or a drying device on several days during the inspection.

15 (h) Defendants fail to exclude pests from their facility to protect against food
16 contamination. *See* 21 C.F.R. § 117.35(c). FDA investigators observed, among other things, winged
17 insects on equipment and portions of the facility's production wall.

18 (i) Defendants do not train employees in the principles of food hygiene and food
19 safety or have records documenting training of qualified individuals. *See* 21 C.F.R. § 117.4.

20 17. Additionally, FDA investigators took eighty-five environmental swabs from Defendants'
21 facility, of which four tested positive for the presence of *L. mono*. One of the positive swabs came from
22 a food contact surface. FDA analyzed the positive *L. mono* samples using the Whole Genome
23 Sequencing ("WGS") technique, which allows scientists to precisely characterize the complete genome
24 DNA sequence of bacterial pathogens with high-resolution data that can be used to infer the
25 evolutionary relationships (also known as phylogeny) within a bacterial species. This allows scientists
26 to determine, with a high degree of certainty, whether two pathogen samples originated from the same
27 source based on their genomic makeup. WGS is recognized by public health agencies as the molecular

approach having the greatest success and promise for early detection and rapid resolution of bacterial outbreaks associated with contaminated foods. Using that technique, FDA determined that a specific strain of *L. mono* found within the facility in February 2019 matched the strain of *L. mono* found in the facility during FDA's inspection in September-October 2017.

Prior Inspections

18. FDA also inspected Defendants' facility in September-October 2017 and June 2018.

19. FDA investigators observed numerous inadequate sanitation practices during both the September-October 2017 and June 2018 inspections, and issued a Form 483 (Notice of Inspectional Observations) at the conclusion of each. The Forms 483s included observations of the same type of deficiencies observed in the February 2019 inspection, including, but not limited to, the following:

(a) Failure to conduct operations under conditions and controls necessary to minimize the potential for food contamination. In particular, in the 2017, 2018, and 2019 inspections, FDA investigators observed racks of uncovered tofu products coming into direct contact with visibly dirty plastic curtain strips in a doorway;

(b) Failure to clean and sanitize utensils or equipment as frequently and in such a manner as necessary to protect against food contamination; and

(c) Failure to maintain the facility in a clean and sanitary condition and keep it in repair.

20. In addition, FDA detected harmful bacteria in the facility in the September-October 2017 inspection. Specifically, *L. mono* was found in one subsample taken from a cart holding finished tofu product.

NOTICE OF VIOLATIONS AND DEFENDANTS' RESPONSE

21. FDA investigators communicated their concerns with Defendants at the conclusion of the 2017, 2018, and 2019 inspections. Defendants promised to correct deficiencies following each inspection but did not fully complete their promised corrective actions.

22. Following the most recent inspection in 2019, Golden Gate Soy implemented a recall of all hand-packed product within the expiration date of the day they were notified that FDA detected *L.*

1 *mono* in the facility. On March 5, 2019, they submitted a written response to FDA's observations in
 2 which they promised to correct each deficiency. The response, however, is inadequate in numerous
 3 respects. The company has not addressed the root cause of contamination, has not developed written
 4 preventative controls, does not employ anyone with the experience, education or training to oversee
 5 such controls, was unable to provide standard operation procedures for sanitation and other crucial
 6 functions, and has not shown that it has the knowledge or ability to mitigate the food safety hazards and
 7 insanitary conditions FDA has observed.

8 23. In addition to these factors, the repeated observations from 2017, 2018, and 2019, the
 9 detection of harmful bacteria in the facility in the 2017 and 2019 inspections, and Defendants' failure to
 10 implement all promised corrective actions demonstrate that they have failed to significantly address the
 11 insanitary conditions in their facility and will continue to violate the law unless enjoined by this Court.

12 **PRAYER FOR RELIEF**

13 WHEREFORE, Plaintiff respectfully requests that this Court:

14 I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants and each and all of
 15 their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and
 16 all persons in active concert or participation with any of them (including individuals, directors,
 17 partnerships, corporations, subsidiaries, and affiliates), who receive notice of the Court's order from,
 18 directly or indirectly, violating 21 U.S.C. § 331(k), by doing and causing to be done any act that causes
 19 any article of food to become adulterated within the meaning of 21 U.S.C. § 342(a)(4), while such
 20 article is held for sale after shipment of one or more of its components in interstate commerce;

21 II. Order Defendants and each and all of their directors, officers, agents,
 22 representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or
 23 participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries,
 24 and affiliates), who receive notice of the Court's order to cease, directly or indirectly, receiving,
 25 processing, manufacturing, preparing, packaging, holding, and distributing any article of food within
 26 the meaning of 21 U.S.C. § 321(f), at or from Defendants' facility (and any other or new location at or
 27 from which Defendants receive, process, manufacture, prepare, pack, hold, or distribute food), unless

1 and until Defendants bring their operations into compliance with the Act and its implementing
2 regulations to the satisfaction of FDA; and

3 III. Award the United States its costs herein, including the costs of investigation to date, and
4 such other relief as the Court may deem just and proper.

5
6 DATED this 13th day of November, 2019.

7 FOR THE UNITED STATES OF AMERICA:

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9 Assistant Attorney General
10 Civil Division

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12 Deputy Assistant Attorney General

13 GUSTAV W. EYLER
14 Director

15 /s/ Meredith B. Healy
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Complaint for Permanent Injunction

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JS-CAND 44 (Rev. 07/19)

CIVIL COVER SHEET

The JS-CAND 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved in its original form by the Judicial Conference of the United States in September 1974, is required for the Clerk of Court to initiate the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM)

I. (a) PLAINTIFFS

THE UNITED STATES OF AMERICA

(b) County of Residence of First Listed Plaintiff
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)

See Attachment A

DEFENDANTS

GOLDEN GATE SOY PRODUCTS, INC., a corporation; YONG LI CHEN, an individual; and LING HONG TANG, an individual

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY) San Francisco County

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

See Attachment A

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- X1 U.S. Government Plaintiff 3 Federal Question
(U.S. Government Not a Party)
- 2 U.S. Government Defendant 4 Diversity
(Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

	PTF	DEF		PTF	DEF
Citizen of This State	1	1	Incorporated or Principal Place of Business In This State	4	4
Citizen of Another State	2	2	Incorporated and Principal Place of Business In Another State	5	5
Citizen or Subject of a Foreign Country	3	3	Foreign Nation	6	6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
110 Insurance	PERSONAL INJURY	625 Drug Related Seizure of Property 21 USC § 881	422 Appeal 28 USC § 158	375 False Claims Act
120 Marine	310 Airplane	365 Personal Injury - Product Liability	423 Withdrawal 28 USC § 157	376 Qui Tam (31 USC § 3729(a))
130 Miller Act	315 Airplane Product Liability	367 Health Care/Pharmaceutical Personal Injury Product Liability	LABOR	400 State Reapportionment
140 Negotiable Instrument	320 Assault, Libel & Slander	368 Asbestos Personal Injury Product Liability	710 Fair Labor Standards Act	410 Antitrust
150 Recovery of Overpayment Of Veteran's Benefits	330 Federal Employers' Liability	PERSONAL PROPERTY	720 Labor Management Relations	430 Banks and Banking
151 Medicare Act	340 Marine	370 Other Fraud	740 Railway Labor Act	450 Commerce
152 Recovery of Defaulted Student Loans (Excludes Veterans)	345 Marine Product Liability	371 Truth in Lending	751 Family and Medical Leave Act	460 Deportation
153 Recovery of Overpayment of Veteran's Benefits	350 Motor Vehicle	380 Other Personal Property Damage	790 Other Labor Litigation	470 Racketeer Influenced & Corrupt Organizations
160 Stockholders' Suits	355 Motor Vehicle Product Liability	385 Property Damage Product Liability	791 Employee Retirement Income Security Act	480 Consumer Credit
190 Other Contract	360 Other Personal Injury	PRISONER PETITIONS	IMMIGRATION	485 Telephone Consumer Protection Act
195 Contract Product Liability	362 Personal Injury - Medical Malpractice	HABEAS CORPUS	462 Naturalization Application	490 Cable Sat TV
196 Franchise	CIVIL RIGHTS	463 Alien Detainee	465 Other Immigration Actions	850 Securities Commodities Exchange
REAL PROPERTY	440 Other Civil Rights	510 Motions to Vacate Sentence		X890 Other Statutory Actions
210 Land Condemnation	441 Voting	530 General		891 Agricultural Acts
220 Foreclosure	442 Employment	535 Death Penalty		893 Environmental Matters
230 Rent Lease & Ejectment	443 Housing Accommodations	OTHER		895 Freedom of Information Act
240 Torts to Land	445 Amer. w/Disabilities - Employment	540 Mandamus & Other		896 Arbitration
245 Tort Product Liability	446 Amer. w/Disabilities - Other	550 Civil Rights		899 Administrative Procedure Act Review or Appeal of Agency Decision
290 All Other Real Property	448 Education	555 Prison Condition		950 Constitutionality of State Statutes
		560 Civil Detainee - Conditions of Confinement		

V. ORIGIN (Place an "X" in One Box Only)

- X1 Original Proceeding 2 Removed from State Court 3 Remanded from Appellate Court 4 Reinstated or Reopened 5 Transferred from Another District (specify) 6 Multidistrict Litigation Transfer 8 Multidistrict Litigation Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing. (Do not cite jurisdictional statutes unless diversity):

21 U.S.C. § 332(a)
Brief description of cause:

Defendants' food is adulterated under 21 U.S.C. § 342(a)(4) and defendants are therefore violating 21 U.S.C. § 331(k).

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, Fed. R. Civ. P.

DEMAND \$

Permanent Injunction

CHECK YES only if demanded in complaint:
JURY DEMAND: Yes X No

VIII. RELATED CASE(S), IF ANY (See instructions)

JUDGE

DOCKET NUMBER

IX. DIVISIONAL ASSIGNMENT (Civil Local Rule 3-2)

(Place an "X" in One Box Only)

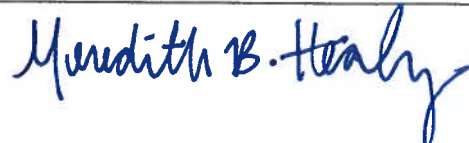
X SAN FRANCISCO/OAKLAND

SAN JOSE

EUREKA-MCKINLEYVILLE

DATE 11/13/2019

SIGNATURE OF ATTORNEY OF RECORD



ATTACHMENT A

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